

# Notice of Allowability

Application No.

09/806,636

Examiner

Simon J. Oh

Applicant(s)

YAMAGUCHI ET AL.

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 29 October 2003.
2. ☒ The allowed claim(s) is/are 2-26 and 28-32.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

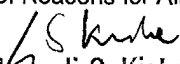
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- 1 ☐ Notice of References Cited (PTO-892)
- 2 ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3 ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. \_\_\_\_\_
- 4 ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

- 5 ☐ Notice of Informal Patent Application (PTO-152)
- 6 ☐ Interview Summary (PTO-413), Paper No. \_\_\_\_\_
- 7 ☒ Examiner's Amendment/Comment
- 8 ☐ Examiner's Statement of Reasons for Allowance
- 9 ☐ Other

  
Gollamudi S. Kishore, PhD  
Primary Examiner  
Group 1500

**EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Warren Zitlau on 11 December 2003.

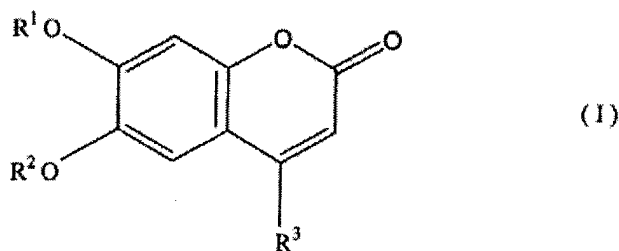
The application has been amended as follows:

New Claim 32 has been drafted as follows:

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32. A controlled-release oral preparation consisting essentially of:

a tablet consisting essentially of a compressed mixture of: a) esculetin, or its derivative as shown by the formula (I),



wherein  $R^1$  and  $R^2$  are individually a hydrogen atom or a saturated or unsaturated aliphatic acyl group having 2-25 carbon atoms or a benzoyl group, and  $R^3$  is a hydrogen atom, hydroxyl group, alkyl group, aryl group, or aralkyl group, or a pharmaceutically acceptable salt thereof as an effective component; and b) a gel-forming polymer base; and

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an enteric coating base on the compressed mixture; and

an insoluble coating base.

In Claim 4, in the second line, the phrase "an enteric coating" has been replaced by the phrase, "the enteric coating".

In Claim 8, in the second line, the phrase "claim 30" has been replaced by the phrase "claim 32"; and in the fourth line, the phrase "an insoluble coating" has been replaced by the phrase "the insoluble coating".

### *Correspondence*

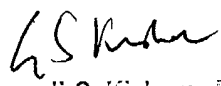
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh  
Examiner  
Art Unit 1615

sjoh

  
J. S. Kishore, PhD  
Primary Examiner  
Group 1600